



Only for use in the administration of these products. Before use, inspect the gloves for any defect or imperfections. Ensure that the gloves fully cover both hands and avoid contact with the product. Gloves for single use only.

Users' Manual of Instructions

Glove Description: Polyethylene Gloves (PE)

Product Reference: SD-PE -001

Size: 13

Hand size	13
Hand circumference (mm)	340 ±5
Hand length (mm)	290 ±5

Intend Use: To provide hand protection in the administration of these products.

Test and Performance:

Category III PPE in conformity with Regulation (EU) 2016/425 on Personal Protective Equipment concerning innocuousness, comfort, solidity, and European harmonized standards EN ISO 374-1:2016+A1:2018; EN ISO 21420:2020.

EN ISO 374-1:2016/A1:2018/Type C



EN ISO374-1:2016/A1:2018/Type C, Performance Level 6: Measured breakthrough time > 480 min

Tested chemical	CAS N °	Letter	Permeation performance levels	Degradation value
Sodium hydroxide 40%	1310-73-2	K	6/6	5.3%
Formaldehyde 37%	50-00-0	T	6/6	11.2%

Type C: The permeation performance shall be at least level 1 against a minimum of one test chemical.

Air and water tightness: conform

AQL sampling level: <1.5

The glove meets the requirements of the standard EN ISO 21420: 2020.

General requirements for work glove Dexterity: 5/5

Instruction for use:

1. Open single package.
2. Wear directly.
3. Ensure that the gloves fully cover both hands and avoid contact with the product as much as possible.

Warnings:

1. The gloves are suitable for hand protection.
2. Before usage, inspect the gloves for any defect or imperfections.
3. Do not use the glove pack past expiry date (see shelf life below).
4. Do not use if package is contaminated.
5. For single use only. Dispose after use.
6. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only and relates only to the chemical tested. It can be different if the chemical is used in a mixture.
7. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures

and pure chemicals.

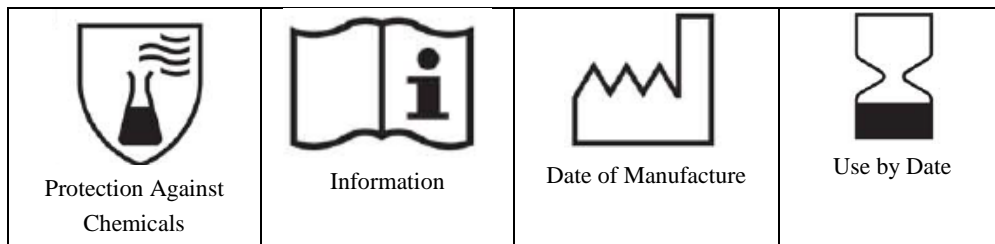
8. When used, protective gloves may provide less resistance to the product due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
9. This model does not contain any substances at levels that are known to, or suspected to, adversely affect user hygiene or health.
10. The protection against risks or hazards which are not mentioned in this document is not warranted. The levels of performance mentioned are only valid for the palm of the glove. The levels of performance mentioned are only valid for new gloves, not washed, nor regenerated. These levels of performance are obtained from the tests done according to conditions defined by the applicable standards.
11. Hand hygiene: in order to not contaminate the hand with a soiled glove, be sure to remove the glove by pinching it from the base of the wrist to the finger. Slide the fingers inside the second glove and remove the glove. Avoid touching the skin.
12. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation.

Storage:

This glove pack should be stored in a clean, dry room at normal room temperature.

Shelf life: Glove pack valid for five years from the date of manufacture.

Pictogram:



Manufacturer Information:

Company: Shanghai Shengda Medical Applications Co., Ltd.

Address: No. 608, Xingwen Rd., Jiading, Shanghai, China

Tel : 86-21-33517332

Notified Body Information:

EU certification module B and module C2 process was carried out by CTC

4, rue Hermann. Frenkel - 69367 Lyon Cedex 07

Country: France

Phone: +33/4.72.76.10.10

Email: cemarking@ctcgroupe.com

Website: <http://www.ctcgroupe.com/>

Notified Body number: 0075

EU Declaration of Conformity:

The EU Declaration of conformity is available via this link:

<http://www.sh-shengda.com/instructions/>

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